P-18-0212

Chemical Name:		
CASRN:		

ASSIGNMENTS	NAME	DATE
SAT Chair	Doritza Pagan-Rodriguez	06/26/18
HH Hazard Assessor (A)	Keith Salazar	06/26/18
HH Hazard QC Reviewer (A)	William Irwin	06/28/18
HH Risk Assessor FOCUS (B)	Cal Baier-Anderson	07/05/18
HH Risk QC Reviewer (B)	Keith Salazar	07/10/18

Hur	nan Health Report Status:	DATE COMPLETED					

7/31/18: updated to correct risk calculation for worker and general population inhalation risks – initially used incorrect calculator. CBA

11/14/18: Corrected typographical errors in calculator K. Salazar

11/26/18: Corrected typographical errors in calculator K. Salazar

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1 HUMAN HEALTH SUMMARY

EPA estimated the human health hazard of this chemical substance based on its estimated physical/chemical properties, and by comparing it to structurally analogous chemical substances for which there is information on human health hazard.

Based on the hazard determination and available quantitative and qualitative risk information, EPA concludes that there is risk for the PMN substance for health effects via inhalation. The risk estimates for this chemical are for the intended conditions of use.

1.1 Hazard Summary

- Absorption of the neat material is nil all routes based on pchem; if in solution, absorption of the LMW fractions is poor all routes based on pchem.
- There are no data on the PMN substance or close analogs representing the PMN substance as a whole. The hazard assessment is based on data on the cation and information provided in the SDS.
- Concern for portal of entry effects (GI, lungs, eyes, dermal contact), systemic effects (reduced body weight, ocular effects, oral exposures) and potential developmental toxicity (oral and inhalation exposure).

1.2 Risk Summary

1.2.1 Workers

- Risks were identified for workers for health effects (decreased body weight) via inhalation based on analog data (MOE = 80, Benchmark MOE = 100, Fold Factor = 1.3, Recommended APF = 10).
- Risks for irritation for workers via ocular, respiratory and dermal exposure cannot be quantified due to lack of dose-response information for this hazard. However, exposures can be controlled by the appropriate use of personal protective equipments (PPE), such as gloves, eye protection, and a respirator with an APF of 10. EPA expects that workers will use appropriate PPE consistent with the Safety Data Sheet prepared by the submitter, in a manner adequate to protect them. Therefore, EPA does not expect unreasonable risk for the irritation endpoint.
- Risks were not identified for workers for reproductive/developmental effects via dermal exposure, based on analog data (MOE_{dermal} = 2660, Benchmark = 1000).

1.2.2 General Population

Risks were not identified for general population for portal of entry, systemic toxicity or reproductive/developmental effects via inhalation or oral exposure, based on analog data (adult MOE=9,760,000, infant MOE= 2,320,000; benchmark MOE=1000; inhalation MOE=3.0E+06; benchmark MOE=100).

1.2.3 Consumers

Consumer risks were not evaluated because consumer uses were not identified as conditions of use.

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1.3 Potentially Useful Information:

1.3.1 Assumptions and Uncertainties

Absorption of the PMN is based on p-chem properties

There are no measured data on the PMN substance itself.

Health effects are based on of the PMN.

1.3.2 Potentially Useful Information

Potentially useful information would inform understanding of:

Absorption

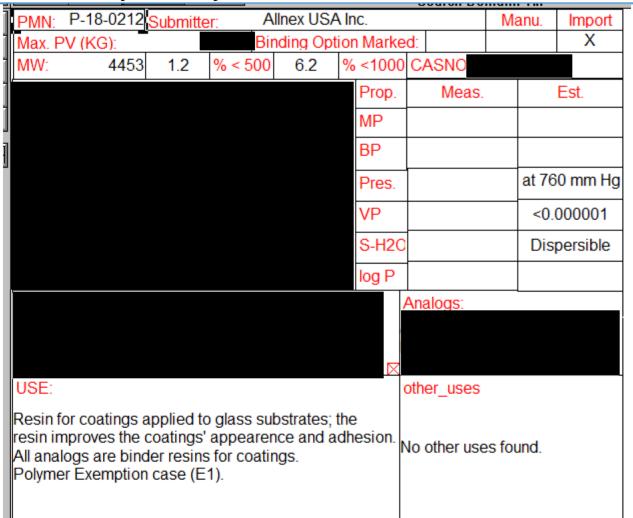
Specific target organ toxicity

Developmental, reproductive toxicity

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2 HUMAN HEALTH HAZARD- PART A

2.1 Chemistry Summary



2.1 SAT Summary

2.1.1 Absorption

Absorption of the neat material is nil all routes (pchem); if in solution, absorption of the LMW fractions is poor all routes (pchem).

2.1.2 SAT Health Summary

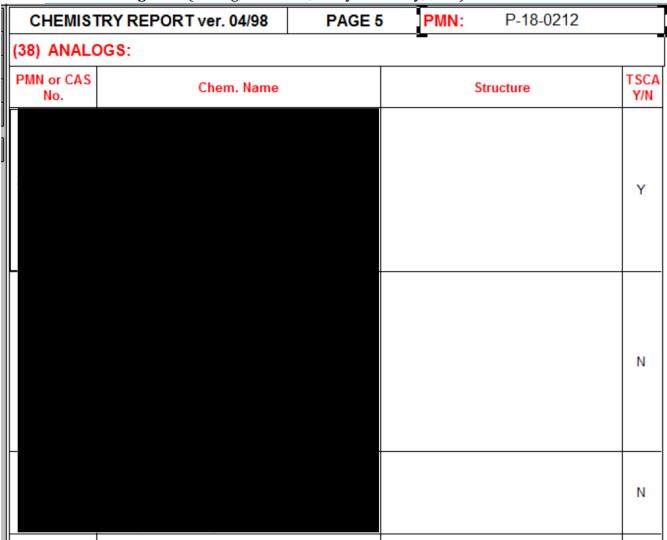
Concern for portal of entry effects, systemic effects and potential developmental toxicity based on data on cation.

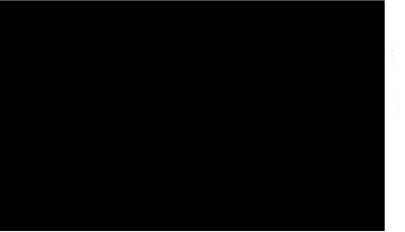
2.1.3 PMN Data (Study summary, POD)

None provided

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2.1.4 Analog Data (analog, structure, study summary, POD)





HEALTH: Absorption nil all routes based on pchem;

- concern for lung toxicity if inhaled based on high molecular weight
- low-moderate concern for toxicity;

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- TOXNET indicates that transient corneal opacity, changes in respiratory and olfactory epithelium of the
 nasal cavity, body weight loss and potential developmental toxicity effects (only one fetal variation was
 elevated in the high dose group) have been observed in animal studies.
- From ECHA database:
 - OECD 413: NOAEC of 24 ppm (87.6 mg/m³) based on 13-week subchronic study in F344 rats exposed to 0, 8, 24, 76ppm CMEA for 6hr/day, 5 days/week for 13 weeks that observed histopathologic lesions of the respiratory and olfactory epithelium.
 - OECD 421/414: DMEA by whole-body exposure in pregnant F344 rats at 0, 10, 30, or 100ppm during GD 6-15 resulted in maternal toxicity (reduced body weight, reduced weight gain, ocular effects (GHS category 2A for eye irritation)) at 30 and 100ppm with no evidence of embryonic or fetal toxicity. Fetal body weights/litter were increased at 100ppm. Developmental NOAEC is 30 ppm. Maternal NOAEC is 10ppm (36.4 mg/m³).
- (OECD 414/421)

The test substance was administered to time-mated female rats orally by gavage from GD 6 through GD 19 (prenatal study part) or GD 6 through PND 3 (postnatal study part). The dose levels were 0 (control: 10 animals), 300 (dose group 1: 10 animals) and 600 mg/kg body weight/day (dose group 2: 20 animals).

For the prenatal study part, selected dams of each group (5 animals of the control group, 5 animals of dose group 1 and 10 animals of dose group 2) were sacrificed on GD 20; dams and fetuses were examined.

For the <u>postnatal study part</u>, the remaining dams were allowed to litter and rear their pups until PND 4. On PND 4, all pups were sacrificed and examined grossly.

- LOAEL of 300 mg/kg-day based on stomach erosions/ulcera in dams, increased postimplantation loss, increased resorptions at 300 mg/kg-day
- **2.1.5** Other Information (SDS, structural alert or component of interest, basis, etc.)

SDS:

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2. HAZARDS IDENTIFICATION

LABEL ELEMENTS

Hazard Statements Precautionary Statements Hazards Not Otherwise Classified (HNOC), Other Hazards Not applicable

3. COMPOSITION/INFORMATION ON INGREDIENTS

HAZARDOUS INGREDIENTS

Component / CAS No.	%	GHS Classification	Carcinogen
Dipropylene glycol methyl ether 34590-94-8	<= 5.2	Flam. Liq. 4 (H227)	-

11. TOXICOLOGICAL INFORMATION

Likely Routes of Exposure: Skin, Eyes, Oral.

PRODUCT TOXICITY INFORMATION

ACUTE TOXICITY DATA

LOCAL EFFECTS ON SKIN AND EYE

Acute Irritation dermal Not irritating
Acute Irritation eye No data

ALLERGIC SENSITIZATION

Sensitization Skin No data Sensitization respiratory No data

GENOTOXICITY

Assays for Gene Mutations

Ames Salmonella Assay No data

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Notes:

- At pre-SAT/SAT, the PMN was not identified as a lung toxicant based on pchem properties, lack of structural alerts and because it is not expected to behave as a surfactant in the lungs.
- PMN substance contains about cation moiety and acid.

2.1.6 Exposure Routes of Interest

Ro	Route of Interest								
X	Inhalation:								
X	Dermal:								
Х	Ingestion:								

2.2 Human Health Category (From US EPA 2010 document)

Chemical Category: Not applicable

Reference:

2.3 Point of Departure Selected and Basis

POD type: NOAEC	
POD Value: 36.4 mg/m ³	
POD Chemical:	
POD Route: inhalation	
POD Hazard Endpoint: Maternal toxicity (reduc	ed body weight, reduced weight gain, ocular effects)
POD Basis: Lowest available POD for inhalation	exposures
POD Benchmark MOE: 100	
Reference: ECHA database accessed 06/26/18	
2.3.2 POD for	of PMN) for oral exposures
POD type: LOAEL	
POD Value: 300 mg/kg-day	
POD Value: 300 mg/kg-day POD Chemical:	
POD Chemical: POD Route: oral	in dams, increased post-implantation loss, increased
POD Chemical: POD Route: oral	in dams, increased post-implantation loss, increased
POD Chemical: POD Route: oral POD Hazard Endpoint: stomach erosions/ulcera	
POD Chemical: POD Route: oral POD Hazard Endpoint: stomach erosions/ulcera	

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3 HUMAN HEALTH RISK (PART B)

3.1 USES and EXPOSURES

3.1.1 Uses

Resins

3.1.2 Worker Exposure

3.1.2.1 Inhalation

Negligible

Particulates

Potential Dose Rate: mg/day over days/yr

3.1.2.2 Dermal

Exposure to Liquid at concentration

High End:

> Potential Dose Rate: mg/day over days/yr

> Lifetime Average Daily Dose: mg/day over days/yr

> Average Daily Dose: mg/day over days/yr

> Acute Potential Dose: mg/day over days/yr

3.1.3 General Population Exposure:

3.1.3.1 Drinking Water

Drinking water ingestion with ADR as high as 3.99e-04 mg/kg/day and LADD as high as
 1.33e-05 mg/kg/day

3.1.3.2 Fish

• Fish ingestion exposures are not calculated if a chemical is not released to surface water or the bioconcentration factor is negligible.

3.1.3.3 Air/Inhalation

- Inhalation from fugitive air releases with ADR as high as 3.66e-02 mg/kg/day and LADD as high as 8.67e-04 mg/kg/day
- Inhalation from fugitive air releases with ADR as high as 3.66e-02 mg/kg/day and LADD as high as 8.67e-04 mg/kg/day

3.1.4 Consumer Exposure

No identified consumer uses.

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3.2 RISK CALCULATIONS

Absorption of the neat material is nil all routes based on pchem; if in solution, absorption of the LMW fractions is poor all routes based on pchem. Oral, stomach erosions/ulcera in dams, increased post-implantation loss, increased resorptions, LOAEL = 300 mg/kg bw/day Inhalation, Maternal toxicity (reduced body weight, reduced weight gain, ocular effects), NOAEL = 36.4 mg/m3

3.2.1 Worker Calculations

Worker M	Vorker Margin of Exposure (MOE) Calculations using Animal inhalation POD and Engineering Report PDR														
							Hun	nan							
								Breat	hing					Benchmark	Endpoint
	Animal	or Huma	n POD		Worker Ex	oosure		Rat	es					MOE	Type
Exposure	POD Conc.	POD	POD	Exposure	Total Worker	Worker	Exposure			Structural	POD Conc -	Exposure	Margin of	100	NOAEL
Route	mg/m ³	Period	Duration	mg/day	Breathing	Exposure	Duration			Alert as %	Duration &	TWA	Exposure		
		hrs/day		Potential		Duration				of PMN	Breathing	mg/m ³	MOE		
				Dose Rate	PDR	Hours/Da					Rate				
				(PDR)	Exposure	У		품	er		Correction				
					Period m ³			fa	ž		Scenario _{HEC}				
								ЭΟ	Š		mg/m ³				
Inhalation														Fold Factor =	1.3

Worker Ma	Vorker Margin of Exposure (MOE) Calculations using Animal Oral POD and Engineering Report PDR														
											Benchmark	Endpoint			
	Ani	mal or Hun	nan	Human							MOE	Type			
Exposure	POD	POD	POD	Exposure	Exposure	Exposure	Body	Exposure	Structural	Margin of	1000	LOAEL			
Route	mg/kg-day	Exposure	Route %	mg/day	Duration	Route %	Weight	mg/kg-	Alert as %	Exposure					
		Duration	Absorp	Potential	Days/Wk	Absorp	kg	day	of PMN	MOE					
		Days/Wk		Dose Rate											
				(PDR)											
Dermal										2664.0					

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3.2.2 General Population Calculations

Population Margin	Population Margin of Exposure (MOE) Calculations using Animal Inhalation POD and Exposure Report ADR														
										Benchmark	Endpoint				
	Animal or Human			Human						MOE	Туре				
Exposure	POD	POD	POD	Exposure	Exposure	Exposure			Margin of	1000	LOAEL				
Route	mg/kg-day	Exposure	Route %	mg/kg-day				Alert as %	•						
		Duration	Absorp		Days/Wk	Absorp	Subpopulations	of PMN	MOE						
		Days/Wk		Rate (ADR)											
Drinking Water									9,764,671.42						
									, , ,						
Drinking Water	+								2,324,921.77						

General Popul	General Population Margin of Exposure (MOE) Calculations using Animal Oral POD and Exposure Report ADR														
										Benchmark	Endpoint				
	Anim	al or Hum	an POD	Pop	Population Exposure					MOE	Туре				
Inhalation	POD Conc.	POD	POD	Exposure	Population	Exposure	Structural	POD Conc -	Margin of	100	NOAEL				
Exposure	mg/m ³	Period	Duration	(24-hr	Exposure	Duration	Alert as %	Duration	Exposure						
Scenario		hrs/day	days/wk	conc.)	Duration	Days/Wk	of PMN	Correction -	MOE						
				(ug/m3)	Hours/Day			Scenario _{HEC}							
								mg/m ³							
Fugitive air									3.0E+06						

3.2.3 Consumer Calculations

Consumer risks were not evaluated because consumer uses were not identified as conditions of use.

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